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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,720	01/17/2006	Haruo Imawaka	Q92718	1473

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
ZUCKER, PAUL A	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,720	IMAWAKA ET AL.	
	Examiner	Art Unit	
	Paul A. Zucker	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 20 December 2007.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Applicant's cancellation of claims 11-18 is acknowledged.
4. Claims 1-10 and 19 are pending.
5. The rejection under 35 USC § 112, second paragraph, set forth in paragraph 2 of the previous Office Action mailed 13 September 2007 is withdrawn as moot in view of Applicants' cancellation of claim 13.
6. The rejection under 35 USC § 112,first paragraph, set forth in paragraph 3 of the previous Office Action mailed 13 September 2007 is withdrawn as moot in view of Applicants' cancellation of claims 11-18. NOTE: Claim 19 was omitted from this rejection by clerical error. Applicants should have recognized that since the limitations of claim 19 were addressed, it should have properly been included. The following rejection is therefore made FINAL.
7. Claim 19 is finally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of some neurodegenerative disorders, does not reasonably provide enablement for prevention of any disorder or treatment of disorders such as brain cancer or Down's Syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

a. the breadth of the claims: In the instant case the claims are extremely broad encompassing methods for the prevention of any form of neurodegenerative condition including brain cancer in all its various forms, Down's disease or syndrome, Creutzefeld-Jacob disease, Huntington's disease, etc.

b. the nature of the invention: The instantly claimed invention involves influencing astrocytes in the brain. While this may, in principle, have a therapeutic consequence, it is far from clear that demonstration of an *in vitro* effect will result in an *in vivo* effect. This is especially true given the broad range of disease states recited, Brain cancer, for example, encompasses a large number of conditions each with its own characteristics.

c. the state of the prior art: the state of the prior art is such that many of the disease states recited such as brain cancer in all its various forms, Down's disease or syndrome, Creutzefeld-Jacob disease, Huntington's disease, etc, have no known treatment and no known method of prevention by pharmaceutical means. For example, there is no pharmaceutical method for the prevention of Down's syndrome, which is a genetic disorder.

e. the amount of direction provided by the inventor: The inventor provide no direction for the use of the compounds of the invention for the treatment of any disease state.

f. the existence of working examples: The only working examples provided are directed to the content of S100β in astrocyte cells in culture. No examples of treatment of disease states is provided

Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention.

8. The rejections under 35 USC § 102 set forth in paragraphs 4 and 5 of the previous Office Action mailed 13 September 2007 are withdrawn in view of Applicants' amendment.

9. The rejection under 35 USC § 103 set forth in paragraph 6 of the previous Office Action mailed 13 September 2007 is withdrawn in view of Applicants' amendment.

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New Rejections

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 and 5 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Manny et al (Tetrahedron, Reinvestigation of the Sulfuric Acid-Catalyzed Cyclisation of Brominated.2-Alkyllevulinic Acids to 3-Alkyl-5-methylene-2(5H)-furanones, 1997, 53(46), pages 15813-15826). Manny discloses (Page 15822, lines 20-42) the compounds 2-(2-oxopropyl) hexanoic acid, 2-(2-oxopropyl) octanoic acid and 2-(2-oxopropyl) tetradecanoic acid all of which are compounds of instantly claimed formula (I). The material is presumed to be racemic and therefore both stereoisomers are present. Manny therefore anticipates claims 1-3 and 5.

11. Claims 1-3, 5 and 9 are finally rejected under 35 U.S.C. 102 (b) as being anticipated by English et al (Journal of the American Chemical Society, The Synthesis of Some 1-Cyclopentenealdehydes, 1949, 71, pages 3310-3313). English discloses (Page 3312, column 1, lines 48-60) the racemic compound 2-*n*-propyladipic acid in aqueous solution. The Examiner considers this to be a pharmaceutical solution of both stereoisomers of a compound of instantly claimed formula (I). English therefore anticipates claims 1-3, 5 and 9.

12. Claims 1-4, 6 and 8-10 are finally rejected under 35 U.S.C. 102 (b) as being anticipated by Dobner et al (Chemistry and Physics of Lipids Synthesis of Deuterium-Labeled Methyl-branched Fatty Acids, 1991, 60(1), pages 21-28, Abstract with STN printout). Dobner discloses (See STN printout) the compound 14-hydroxy-2-propyl tetradecanoic acid which corresponds to a compound of formula (I-2). The Examiner considers the compound itself to represent a pharmaceutical composition with any residual traces of solvents and impurities corresponding to a carrier.

13. Claims 1-4, and 6-10 are finally rejected under 35 U.S.C. 102 (b) as being anticipated by Yoneda et al (Chemistry Letters, Reaction Behavior of Carbon-Carbon and Carbon-Hydrogen Bonds in Super Acids, 1983, 1, pages 19-20). Yoneda discloses (Page 20, Table, 5th row, 2nd column of products) a compound of Formula (I-2)) the compound 7-oxo-2-propyl-octanoic acid which corresponds to a compound of formula (I-2). Both stereoisomers are presumed present. The Examiner considers the compound itself to represent a pharmaceutical composition with any residual traces of solvents and impurities corresponding to a carrier.

Conclusion

14. Claims 1-10 and 19 are pending. Claims 1-10 and 19 are finally rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner,
Art Unit 1621